K091193

5.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	IsoTis OrthoBiologics, Inc.
TRADE NAME:	ACCELL EVO3C™
COMMON NAME:	Bone Void Filler
CLASSIFICATION NAME:	Resorbable calcium salt bone void filler
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	MQV, MBP
PREDICATE DEVICES:	Accell Family of products - K061880 (Accell DBM100, Accell TBM®, Accell A2i and Accell Connexus®), DYNAGRAFT® II - K040419, ORTHOBLAST® II - K050642 , DBX DBM Mix - K063676, Grafton DBM Orthoblend - K051195

AUG 10 2009

5.1 Substantially Equivalent To:

The Accell Evo3c™ is substantially equivalent in intended use, principal of operation and technological characteristics to the current Accell Family of products (Accell DBM100, Accell TBM®, Accell A2i and Accell Connexus®); 510(k) – K061880, DYNAGRAFT® II; 510(k) – K040419, ORTHOBLAST® II; 510(k) – K050642, DBX DBM Mix; 510(k) – K063676, and Grafton DBM Orthoblend 510(k) – K051195.

5.2 Description of the Device Subject to Premarket Notification:

The Accell Evo3c™ is an extension to the Accell Family of products cleared under 510(k) K061880. The Accell Family of products, including Accell Evo3c™, contain human demineralized bone matrix (DBM) in particulate and dispersed forms. The Accell Evo3c™ is the same as Accell A2i, submitted under 510(k) K061880, with the exception of the inclusion of cancellous bone chips which are added as an osteoconductive scaffold. The Accell A2i is marketed under the brand name "Accell Evo3™," hence the "c" in Accell Evo3c™ denotes the inclusion of cancellous chips in the formulation.

5.3 Indication for Use:

Accell Evo3c™ is intended for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. Accell Evo3c is indicated for use as a bone graft extender in the posterolateral spine, extremities and pelvis, or as a bone void filler in the extremities and pelvis. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone.

5.4 Technical Characteristics:

The Accell Evo3c™ and Accell Family of products (K061880) utilize ground and demineralized, human cortical bone (DBM) in the formulation of the product. The Accell Evo3c™ includes cancellous chips which act as an osteoconductive scaffold. The DBM component exhibits osteoinductive potential in validated animal and/or *in vitro* models. It is unknown how the osteoinductive potential, measured in these validated models, will correlate with clinical performance in human subjects.

5.5 Performance Data:

All necessary verification testing has been performed for the Accell Evo3c™ product to assure substantial equivalence to the predicate device.

5.6 Osteoinductive Potential

Each lot of DBM used to manufacture the Accell Evo3c™ and the Accell Family of products is tested for osteoinductive potential using a quantitative *in vitro* assay. The *in vitro* assay has been validated to correlate to an athymic mouse osteoinductive potential assay. It is unknown how osteoinductive potential measured via the *in vitro* or athymic mouse assays will correlate with human clinical performance.

5.7 Viral Inactivation Validation

The methods for processing of the DBM contained in Accell Evo3c™ and the Accell Family of products were evaluated for their viral inactivation potential. A selected panel of viruses representing various virus types, sizes, shapes and genomes were evaluated. The viral inactivation testing demonstrated suitable inactivation potential of the processing methods for a wide range of potential viruses.

Viral Inactivation Validation: The methods for processing of the DBM contained in Accell Evo3c were evaluated for their viral inactivation potential. A selected panel of viruses representing various virus types, sizes, shapes and genomes were evaluated. The viral inactivation testing demonstrated suitable inactivation potential of the processing methods for a wide range of potential viruses. . The Evo3c product contains cancellous bone which has been added to the demineralized bone matrix. Since the cancellous bone chips are not demineralized, the degree of viral inactivation of this component is not fully known The cancellous bone has been processed in antimicrobial, antiviral, and antiseptic solutions which are recommended by the American Association of Tissue Banks (AATB) to reduce the risk of transmissible viral diseases from human tissue products. The risk of disease transmission with the cancellous bone component remains low due to multiple safeguards including donor screening, serologic testing, tissue cleaning process, and terminal sterilization of the finished device.

5.8 Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing

intended use, principle of operation and overall technological characteristics, the Accell Evo3c™, has been determined by IsoTis OrthoBiologics to be substantially equivalent to an existing legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

IsoTis OrthoBiologics, Inc.
Division of Integra LifeSciences Corporation
% Ms. Carroll Councilman
Director Quality Assurance and Regulatory Affairs
2 Goodyear, Suite A
Irvine, California 92618

AUG 10 2009

Re: K091193
Trade/Device Name: Accell Evo3c™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: II
Product Code: MQV, MBP
Dated: June 2, 2009
Received: June 3, 2009

Dear Ms. Councilman :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K091193

Device Name: Accell Evo3c™

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091193